

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 15, 2010 has been entered.

Claims 1-4, 6-7, 11, 14-19, 21-26 and 29-31 are allowed.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: a liquid, aqueous composition comprising (i) a factor VII polypeptide; (ii) an agent suitable for keeping pH in the range of from about 5.5 to about 7.0; (iii) a calcium salt in a concentration of at least 200 mM is both novel and unobvious over the prior art of record.

The IDS filed on March 15, 2010 has been considered. None of the references submitted on the IDS on March 15, 2010 either anticipates or renders obvious the claimed invention. The closest art filed with the IDS is Osterberg et al (WO 94/26286). The art teaches factor VIII in an aqueous solution (see abstract). The reference teaches that the pH of the solution is suitably 6.5 to 8.5, and preferably about 7 (see p. 6, line

20). Further, a non-ionic surfactant is present in the solution, such as a poloxamer or polyethylene sorbitan fatty acid ester, in an amount of at least 0.01 mg/ml (see p. 6, lines 22-29). The solution can further contain sodium or potassium chloride, in an amount of more than 0.1 M (see p. 6, lines 31-32). Additionally, calcium was added as calcium chloride, but other salts such as calcium gluconate, calcium glubionate or calcium gluceptate can also be used, in an amount of more than 0.5 mM (see p. 6, lines 34-36 and p. 7, lines 1-2). The reference teaches that the final drug product preferably comprises an aqueous solution containing i) coagulation factor VIII, ii) at least 0.01 mg/ml of polyoxyethylene sorbitan fatty acid ester, iii) sodium chloride, in an amount of more than 0.1 M, iv) calcium salt, in an amount of more than 0.5 mM, v) an amino acid, such as L-histidine, in an amount of more than 1 mM, and vi) a mono- or disaccharide or a sugar alcohol (see p. 7, lines 9-16 and Tables 1-4). The reference teaches that factor VIII was eluted with 0.05 M L-histidine, 4 mM CaCl_2 , 0.6 M NaCl, pH 6.8 (see p. 8, line 37 and p. 9, line 1). The highest amount of calcium chloride used in the reference is 4 mM. From the teachings of the reference, one of ordinary skill in the art would not be motivated to increase the calcium chloride concentration to at least 200 mM. Therefore, the art does not anticipate or renders obvious the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. Claims 1-4, 6-7, 11, 14-19, 21-26 and 29-31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654